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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,536	11/28/2001	Jesus W. Casas-Bejar	P-7109.03 C1	6231

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EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	09/998,536	CASAS-BEJAR ET AL.	
	Examiner	Art Unit	
	Matthew F DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/13/02 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, *the different layers that make up the medical electrical lead, as well as where the drug is disposed must be shown* or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Specification

2. The amendment filed 1/03/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: there is no mention in the specific of the terms "active agent".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6, 11, 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The terms "active agent" is not found in the specification and drawings of the claims. The examiner is not sure whether the active agent is a drug or a compound that is used during the formation of the lead body such as an organic solvent or another compound. Since there is no support in the specification or drawings a lack of written description has occurred.

The examiner would also like to note that the limitation of the "overcoating is chosen such that said polymer and active agent are free of micron sized particulates" is not well defined in the specification. There is no disclosure with how to make an overcoating with no micron-sized particulates. The specification fails to teach how one of ordinary skill in the art would make an overcoating with an "active agent" and still have "no micron sized particulates."

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The claims recite an active agent not being used to form the insulative lead body, but there is no mention of this in the specification to help clarify the mean of active agent. It an active agent a drug, or solvent. If so then how could

Priority

8. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading, "This is a continuation of Application No. 09/063227, filed 4/20/98." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

9. There seems to be a typographical error, which states this case is a continuation from application number 09/063277, but the application number should be 09/063227.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-6, 11, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724), and further in view of Fearnot et al (US 5,609,629).

Helmus teaches substantially all the claimed subject matter including an implantable medical device (figure 1, col. 3, Line 31), having a tissue-contacting surface formed of polyurethane or silicone (col. 2, Lines 41-42), which has a drug such as heparin (col. 6, Line 51) or a steroid (col. 6, Line 55) intimately mixed into it (col. 4, Lines 20-24 and col. 9, Lines 45-46). Note that col. 7; lines 57-62 specify the OUTER layer, not the reservoir layer. In col. 7, lines 57-62, Helmus teaches that the agent in the outer layer is put there to produce a "gradual release elect" alluding to the slower release of the agent at first from the outer layer and gradual increase in the release rate as the more concentrated stores of the same agent start to seep through the outer layer from the inner reservoir layer. Since this teaches that the agent in the outer layer can be the same as in the inner layer, Helmus' teaching of the reservoir agent being a steroid (col. 6, line 55) is interpreted as referring to physiologically active agents in BOTH the reservoir and outer layer.

Helmus teaches all the claimed subject matter except for the steroid being a glucocorticosteroid such as dexamethasone. Fearnot teaches the use of dexamethasone in a drug embedded outer layer of a catheter. It would have been obvious to one of ordinary skill in the art to use dexamethasone as taught by Fearnot as one of the steroids broadly mentioned by Helmus (col. 6, line 54-55) since dexamethasone is a well-known anti-inflammatory steroid, and as demonstrated by Helmus it is known to use it as the bioactive component of a bioactive surface on a catheter.

Response to Arguments

12. Applicant's arguments filed 1/30/05 have been fully considered but they are not persuasive.

Due to the indefinite language of the claims and lack of disclosure in the specification the examiner interprets the claim to have two layers were the first layer is a non-porous polymer intimately mixed with a drug, and a second layer over the first layer.

The examiner would also like clarification as to how the overcoating and lead body are made, because it would seem impossible to not allow any micron sized particulate into the polymer since air might become trapped into the polymer, or some other particulate could become trapped into the polymer.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
Art Unit 3763
April 15, 2005



NICHOLAS D. LUCCHESI
SUPERVISOR
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